

REMARKS

Claims 1-3 and 5-15 were pending prior to this Response. By the present communication, no claims have been added or canceled, and claim 1 has been amended to define Applicants' invention with greater particularity. Support for the amended claims may be found in the specification as filed. As such, the amendments do not raise any issues of new matter and the amended claims do not present new issues requiring further consideration or search. Applicants respectfully request entry of the amendments set forth in this response under 37 C.F.R. §1.116. Accordingly, upon entry of the present amendment, claims 1 and 5-15 will be pending in this application.

Rejections under 35 U.S.C. §112, First Paragraph

Applicants respectfully traverse the rejection of claims 1-3 and 5-15 under on 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Office Action alleges that the genus of agents having inhibitory function of myostatin activation is structurally diverse as it broadly encompasses many mutants and variants comprising the functions having different structures. Without acquiescing to the reasoning offered by the Office, and in order to expedite prosecution of the instant application, Applicants have amended claim 1 to limit the metalloprotease to bone morphogenic protein-1 (BMP-1), and the agent to a peptide selected from the group consisting of SEQ ID NO: 9-22 and 23. Support for the amended claim language may be found at, among others, Examples 3 and 4 of the specification as filed.

With regard to the allegation that a single representative species of myostatin is disclosed in the specification (see Office Action, page 4), Applicants respectfully direct the Examiner's attention to paragraph [0036] of the specification as filed, which discloses that,

Promyostatin polynucleotides and encoded polypeptides are *exemplified* herein by human promyostatin (SEQ ID NOS:1 and 2; pro peptide is amino acid residues about 20 to 263), bovine promyostatin (SEQ ID NOS:3 and 4; pro peptide is amino acid residues about 20 to 262), chicken promyostatin (SEQ ID NOS:5 and 6; pro peptide is amino acid residues about 20 to 262), and zebrafish

promyostatin (SEQ ID NOS:7 and 8; pro peptide is amino acid residues about 20 to 262). (Specification, paragraph [0036], emphasis added).

Furthermore, the specification discloses that the methods of the invention “can be practiced with respect to any subject that expresses myostatin, including vertebrates and invertebrates.”

(Specification, paragraph [0072]). Accordingly, in view of the list of subjects disclosed in paragraph [0072], and Examples 3 and 4 of the specification as filed, Applicants respectfully submit that the specification satisfies the written description requirement with regard to the amended claims. Withdrawal of the rejection is respectfully requested.

Applicants respectfully traverse the rejection of claims 1-3 and 5-15 under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the enablement requirement. Specifically, the Office Action alleges that the specification is not enabling for a method of modulating any myostatin activation (any metalloprotease specific) by using any agent that increases or decreases proteolytic cleavage of the pro-peptide, thereby modulating myostatin activation. Without acquiescing to the reasoning offered by the Office, and in order to expedite prosecution of the instant application, Applicants have amended claim 1 to limit the metalloprotease to bone morphogenic protein-1 (BMP-1), and the agent to a peptide selected from the group consisting of SEQ ID NO: 9-22 and 23. Applicants submit that in view of the instant specification, one of skill in the art would not be faced with undue experimentation to produce and test an infinite number of possible agents to practice the invention as claimed. Accordingly, Applicants respectfully submit that the specification satisfies the enablement requirement with regard to the amended claims. Withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. §102

Applicants respectfully traverse the rejection of claims 1-3 and 5-15 under 35 U.S.C. §102(e) as allegedly anticipated by Lee et al. (U.S. PGPUB 2002/0157126A1; hereinafter, “Lee”). To anticipate, a single reference must inherently or expressly teach each and every

element of claimed invention. *In re Spada*, 15 USPQ2d 1655 (Fed Cir. 1990); and *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). M.P.E.P. § 2131.

The Office action alleges that Lee discloses a method of modulating myostatin activation by inhibiting pro-myostatin cleavage by an agent that affects myostatin signal transduction. As discussed above, without acquiescing to the reasoning offered by the Office, and in order to expedite prosecution of the instant application, Applicants have amended claim 1 to limit the metalloprotease to bone morphogenic protein-1 (BMP-1), and the agent to a peptide selected from the group consisting of SEQ ID NO: 9-22 and 23. Accordingly, Applicants respectfully submit that Lee fails to disclose each and every element of the claimed invention, and request withdrawal of the rejection.

In Re Application of:

Lee et al.

Application Serial No.: 10/665,374

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PATENT

Attorney Docket No. JHU1800-3

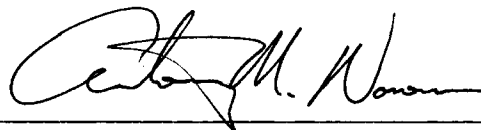
CONCLUSION

In summary, for the reasons set forth herein, Applicants submit that the pending claims clearly and patentably define the invention and respectfully request that the Examiner withdraw all rejections and pass the application to allowance. If the Examiner would like to discuss any of the issues raised in the Office Action, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

The Commissioner is hereby authorized to charge \$1560.00 as payment for the Petition for Three-Month Extension of Time fee (\$1050.00) and Notice of Appeal fee (\$510.00) to Deposit Account No. 07-1896. Additionally, the Commissioner is hereby authorized to charge any other fees that may be due in connection with the filing of this paper, or credit any overpayment to Deposit Account No. 07-1896, referencing the above-referenced Attorney docket number.

Respectfully submitted,

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